

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 1 is currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1-17 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6, 14-17 and 21-25 of U.S. Patent No. 6,316,022. Claims 1-21 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Miranda et al. (U.S. Patent No. 5,656,286). Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Miranda et al. (U.S. Patent No. 5,656,286) in view of Miranda et al. (U.S. Patent No. 5,474,783) and Hortsman et al. (U.S. Patent No. 5,230,898). Reconsideration is requested.

Obviousness-Type Double Patenting

Claims 1-17 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6, 14-17 and 21-25 of U.S. Patent No. 6,316,022. Applicants will address the rejection by filing a terminal disclaimer in the instant application when the claims are indicated as being allowable.

The Present Invention

The present claims relate to transdermal drug delivery compositions for low molecular weight drugs. Claims 2-18 recite that the composition includes one or one or more high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit. Claims 19-21 recite that the composition includes one or one or more high shear resistant acrylic-based polymers having a

shear resistance which is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit. All of the pending claims also recite the feature of “one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperature.”

According to one aspect of the present invention, the present inventors unexpectedly discovered that using the claimed high shear resistance polymer provides the benefits of reducing legginess when using drugs which have plasticizing effects. See the specification at page 22, second paragraph. The present inventors also unexpectedly discovered that a high shear resistance polymer provides for increased solubilization of the drug in the polymer matrix, which in turn allows higher loading of the drug in the transdermal drug delivery system. See page 22, last paragraph.

Claims 1-21 are not anticipated by Miranda

Claims 1-21 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Miranda et al. (U.S. Patent No. 5,656,286).

It is well settled that an invention lacks novelty under 35 U.S.C. § 102 *only* if each and every element of the claim is described or disclosed, either explicitly or inherently, in a single prior art reference. *Finnigan Corp. v. International Trade Com'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999). In fact, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Here, Miranda '286 does not disclose each and every element of the instant claims. Miranda does not disclose a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein one of said one or more polymers is a high shear resistant acrylic-based polymer; and (b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures, which is “substantially free of water and liquids having a boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the low molecular weight drugs,” as set forth in claim 1. The Examiner specifically relies on Example 81 of Miranda '286. Example 81 of Miranda '286 does not disclose the system set forth in claim 1

as it does not disclose that one or more polymers in the system is a “high shear resistant acrylic-based polymer” as claimed. For at least this reason, claim 1 is patentable over Miranda ‘286.

Claims 2-18 recite that the pressure-sensitive adhesive transdermal drug delivery system includes one or one or more high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit. Claims 19-21 recite that the pressure-sensitive adhesive transdermal drug delivery system includes one or one or more high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit.

Miranda ‘286 discloses compositions which include acrylic based polymers such as Duro-Tak 80-1194; Duro-Tak 80-11196, Duro-Tak 80-1197, Gelva 737 and Gelva 738. Duro-Tak 80-1194. (See, Col. 11, lines 13-19). As can be seen from the attached product sheets, none of these acrylic based polymers has a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit, as set forth in claims 19-21 or greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit as set forth in claims 2-18. For at least this reason, Miranda ‘286 does not anticipate claims 2-21.

Claims 1-21 would not have been obvious over the prior art of record

Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Miranda ‘286 in view of Miranda ‘783 and Hortsmann.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

With respect to claim 1, Miranda '286 or Miranda '783 does not disclose or suggest a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein one of said one or more polymers is a high shear resistant acrylic-based polymer; and (b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures, which is "substantially free of water and liquids having a boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the low molecular weight drugs," as set forth in claim 1. Moreover, there is no motivation in these references to arrive at a composition which includes one or more polymers wherein one of said one or more polymers is a high shear resistant acrylic-based polymer; and a therapeutically effective amount a low molecular weight liquid drug where the composition is "substantially free of water and liquids having a boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the low molecular weight drugs." In contrast, each of the references teach that liquids having a boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the low molecular weight drugs may be included in the composition. Thus, if anything, the references teach away from the claimed transdermal system as claimed in claim 1.

With respect to claims 2-21, Miranda '286 and Miranda '783 disclose compositions which include acrylic based polymers such as Duro-Tak 80-1194; Duro-Tak 80-11196, Duro-Tak 80-1197, Gelva 737 and Gelva 738. Duro-Tak 80-1194. (See, Col. 11, lines 13-19). None of these acrylic based polymers has a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit, as set forth in claims 19-21 or greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit as set forth in claims 2-18. There is no teaching in Miranda '286 or Miranda '783 of the importance of high shear resistance when delivering low molecular weight drugs that are liquid at room temperature (*i.e.* volatile drugs.)

There is no suggestion or recognition in Miranda '286 or Miranda '783 of the benefits and unexpected advantages achieved by using the claimed high shear resistant acrylic-based polymer with low molecular weight drugs that are liquid at room temperature. Thus, there

would have been no motivation in Miranda '286 or Miranda '783 for the skilled artisan to modify the acrylic-based polymers disclosed therein to arrive at the claimed acrylic-based polymer that have a shear resistance significantly greater than those disclosed in Miranda. There is nothing in Horstmann that cures the deficiencies of Miranda '286 and Miranda '783.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

Accordingly, in view of the prior art's failure to teach or suggest a transdermal composition having one or more solvent-based high shear resistant acrylic-based polymers having a shear resistance of greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit, as set forth in claims 2-18 or a shear resistance of greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit as set forth in claims 19-21, applicants respectfully submit that claims 2-21 are allowable over the prior art of record.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

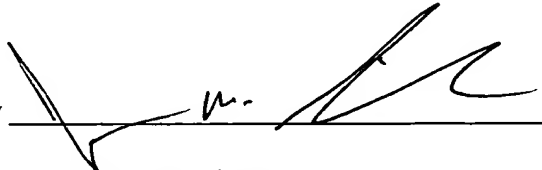
papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R.
§1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 17 June 2004

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By

A handwritten signature in black ink, appearing to read 'James M. Silbermann', is written over a horizontal line.

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